taste panel for transgenic melons
Gillis, Karen
to:
Mike Mendelsohn, jones.kathleen
04/08/2008 04:12 PM
Cc:
"Collis, Philip"
Hide Details
From: "Gillis, Karen" <kgillis@ehs.ufl.edu>
To: Mike Mendelsohn/DC/USEPA/US@EPA, <jones.kathleen@cfsan.fda.gov>,

Cc: "Collis, Philip" <pcollis@ehs.ufl.edu>
Follow Up:
Normal Priority.
History: This message has been replied to and forwarded.

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Would the same recommendations apply?

Attached below is more info.

Thank you,

Karen D. Gillis, MS, RBP

Biological Safety Officer

University of Florida

Division of Environmental Health & Safety

Building 179, Newell Drive

PO Box 112190

Gainesville, FL 32611

T: 352-392-1591

F: 352-392-3647

E: kgillis@ehs.ufl.edu

Request for Approval for tasting

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Re: taste panel for transgenic melons

Mike Mendelsohn to: Gillis, Karen 05/05/2008 09:25 AM

Cc: jones.kathleen, "Collis, Philip"

Karen,

We have been discussing your inquiry internally and should respond within the next two (2) weeks.

Best Regards,

Mike Mendelsohn
Senior Regulatory Specialist
-----"Gillis, Karen" <kgillis@ehs.ufl.edu> wrote: -----

To: Mike Mendelsohn/DC/USEPA/US@EPA, <jones.kathleen@cfsan.fda.gov>
From: "Gillis, Karen" <kgillis@ehs.ufl.edu>
Date: 04/08/2008 04:12PM
cc: "Collis, Philip" <pcollis@ehs.ufl.edu>
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Internal deliberative communication

Fw: taste panel for transgenic melons

Mike Mendelsohn to: Sheryl Reilly, Janet Andersen 06/12/2008 02:59 PM

Sheryl,

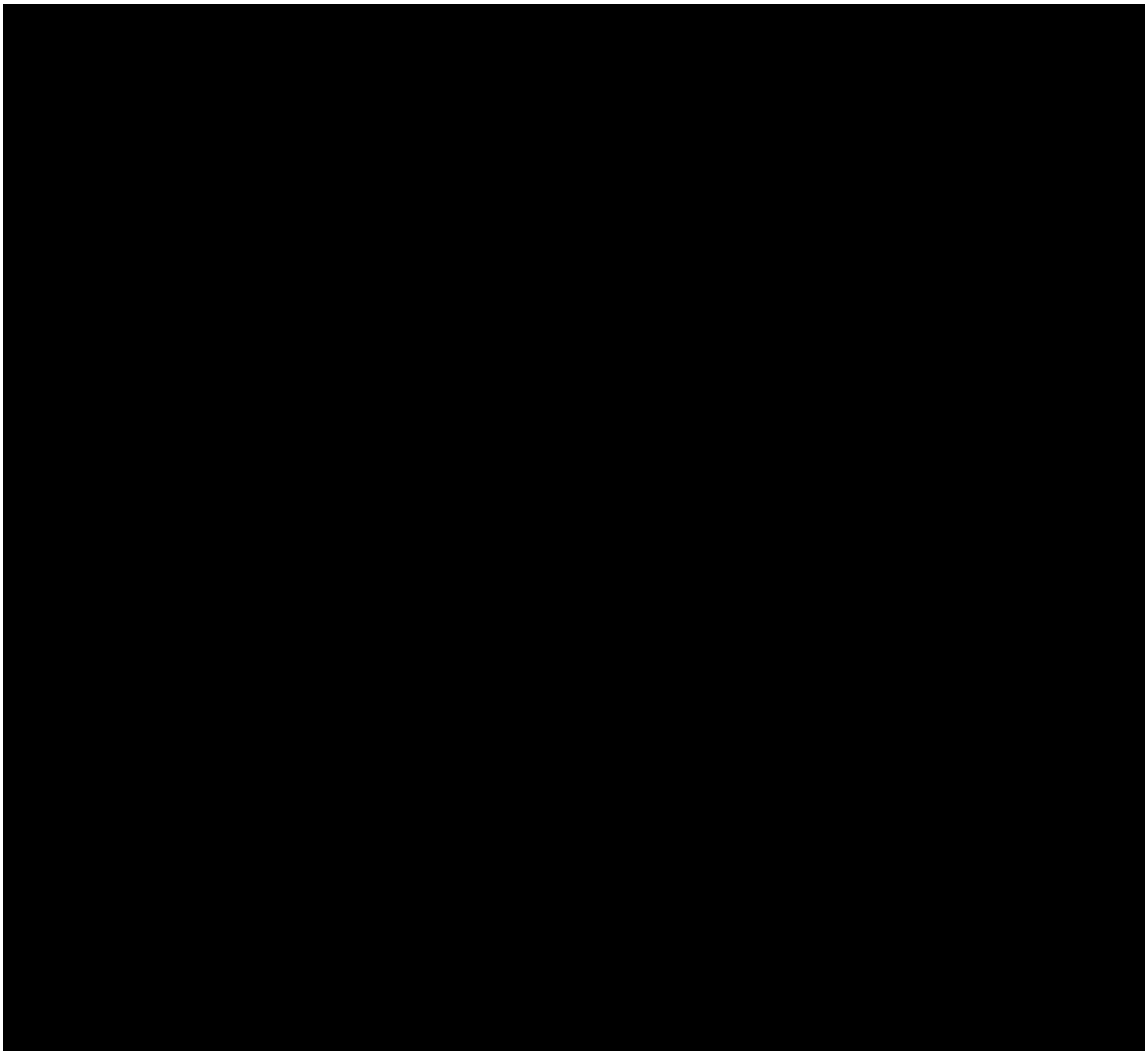
[redacted]

Prepared Response to Karen Gillis of UFL

Ms. Gillis,

[redacted]

Internal deliberative communication



----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 06/12/2008 02:17 PM -----

"Gillis, Karen" <kgillis@ehs.ufl.edu>

04/08/2008 04:12 PM

To Mike Mendelsohn/DC/USEPA/US@EPA, <jones.kathleen@cfsan.fda.gov>

cc "Collis, Philip" <pcollis@ehs.ufl.edu>

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Sheryl Reilly to: kgillis 06/16/2008 03:24 PM
Cc: mendelsohn.mike, jones.kathleen

Follow Up: Urgent Priority.
History: This message has been forwarded.

Dear Ms. Gillis,

Thank you for your inquiry concerning a taste panel for genetically altered muskmelon.

EPA has determined that the transgenic muskmelon you describe contains a plant-incorporated protectant (PIP), subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). This is because the antisense trait used to regulate ethylene production is considered a plant regulator, as defined under FIFRA Section 2 (v).

(v) PLANT REGULATOR.—The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

As long as the melons used for the taste test are grown on ten or less cumulative acres, an Experimental Use Permit under FIFRA would not be required. Further, an FFDCA tolerance exemption exists under 40 CFR Part 174.507 for "[r]esidues of nucleic acids that are part of a plant-incorporated protectant," If the glyphosate tolerant trait is either from CP4 EPSPS of GOX, PIP inert tolerance exemptions under 40 CFR Part 174.523 and 174.524 for CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase and Glyphosate Oxidoreductase GOX or GOXv247 are already established.

Concerning the human studies issue related to the taste test:

Although a definitive judgment would require review of the protocol, the proposal appears to meet the regulatory definition of "research with human subjects" and "research involving intentional exposure of a human subject."

If the research is not conducted or supported by any federal department or agency signatory to the Common Rule for the Protection of Human Subjects of Research, it appears the research could be subject to EPA's rules for the protection of human subjects of third-party research, 40 CFR Part 26, subparts K-Q. That means, among other things, that the protocol and supporting

information would have to be submitted for EPA and HSRB review before study execution, and the work would have to be overseen by an Institutional Review Board.

If research with human subjects is conducted or supported by a Federal department or agency subject to the Common Rule, such as USDA, it would be exempt from EPA's third-party rule mentioned above, and would be subject to that department or agency's codification of the Common Rule, which may include provisions concerning possible exemption of certain taste and food quality evaluation and consumer acceptance studies. For USDA that provision can be found in 7 CFR Part 1c. You should contact USDA with respect to the potentially applicable exemption which appears at 7 CFR 1c.101(b)(6):

> *Sec. 1c.101 To what does this policy apply?*
>
> > *(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:*
> >
> > > *(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.*

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Sheryl K. Reilly, Ph.D.
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----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 06/12/2008 02:17 PM -----

"Gillis, Karen" <kgillis@ehs.ufl.edu>

04/08/2008 04:12 PM

To Mike Mendelsohn/DC/USEPA/US@EPA, <jones.kathleen@cfsan.fda.gov>

cc "Collis, Philip" <pcollis@ehs.ufl.edu>

Subject taste panel for transgenic melons

Hi Drs. Mendelsohn & Jones,

I last emailed w/ a similar question in June of 2006, so I'm not even sure this email will reach you – hope so, as you were helpful last time. In 2006, I asked about a taste panel to test a genetically engineered flavor-modified tomato. This time it is a muskmelon that is constructed to be delayed ripening (similar to the FlavrSavr tomato) and has a glyphosate selectable marker.

Neither the EPA nor the FDA regulated consumption of the taste-modified tomato, but you provided guidance suggesting that the researcher should provide evidence of GRAS status, the Institutional Biosafety Committee should evaluate the taste panel request, and an informed consent should be developed and approved by the Institutional Review Board.

Would the same recommendations apply?

Attached below is more info.

Thank you,

Karen D. Gillis, MS, RBP

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Request for Approval for tasting

Previous United States Department of Agriculture/Caribbean Basin Administrative Group (USDA/CBAG) project funding led to the development of two transgenic inbred lines (TGM-AS-1 and TGM-AS-2) of the male parent of 'Galia' muskmelon (Nuñez-Palenius et al., 2005). Fruit which developed on these lines exhibited delayed ripening. The approach used a gene encoding an important regulator enzyme, ACC oxidase (ACO-1), which works in the last step of ethylene synthesis.

Ethylene is a natural plant product that is produced by all plant tissues. It is a hormone that regulates plant growth, development and senescence (Kader, 2002). In fruit

production, it is responsible for fruit ripening and abscission from the plant. The antisense technology used in this research did not involve the introduction of a new component; instead, it shut-off the gene responsible for ethylene production. In this case, the ACC oxidase gene (ACO-1) was antisensed, therefore reducing the level of ethylene synthesis in the fruit. This is not the first introduction of antisense technology to human consumption. Antisense technology helped produce the first genetically engineered commercial food product sold in the U.S. market, the Flavr Savr™ tomato (Kramer and Redenbaugh, 1994).

This research also involved other genetic engineering. An additional gene was inserted for glyphosate, a selectable marker used to identify the genetically engineered plants from the normal plants. The glyphosate gene is currently used in many herbicide-resistant crops that are commercially grown throughout the world (soybean, corn) and no risks have been found with food products of glyphosate-resistant crops (Cerdeira and Duke, 2006; FAO, 2005). The antisense lines have been produced under USDA-approved conditions using standard commercial greenhouse practices at the UF Plant Science Research and Education Unit in Citra, FL.

The initial antisense muskmelon lines from tissue culture produced fruits which ripened either very slowly or essentially not at all and produced less ethylene compared to wild-type fruits. Other postharvest quality characteristics of the transgenic fruit were not significantly different from the wild-type fruit, denoting that the transgenic melons were comparable to the wild-type melons, even with the newly inserted gene. From the transgenic male parental lines, transgenic F_1 'Galia' Antisense ACC-oxidase hybrids were developed. The antisense 'Galia' fruit produce less ethylene than the original hybrid and ripen at a slower rate. Fruit quality characteristics such as Soluble Solids Content, which is a measure of sweetness, are similar to the original 'Galia'. The objective of the proposed taste panel is to determine if the antisense 'Galia' muskmelon is similar in flavor to the original Galia muskmelon.

Taste panelists will be asked to smell and eat four samples of muskmelon, which will each have their own identification number. The samples will be: 1.) Original Galia muskmelon harvested at a fully-ripe stage; 2.) Antisense ACC-oxidase Galia muskmelon harvested at a fully ripe stage; 3.) Original Galia muskmelon harvested prior to full-slip; and 4.) Antisense ACC-oxidase Galia muskmelon harvested prior to full-slip. Panelists will be asked to smell and eat each sample and then answer a series of questions.

Testing will take place at the Food Science facilities in collaboration with Dr. Charlie Sims. Dr. Sims will run the tests using his standard procedures. Volunteers will be given food vouchers or a soft drink as compensation for participation.

We will be happy to address any questions regarding this request.

Further Information on Antisense ACC-oxidase Galia muskmelon:

Nunez-Palenius, H.G., D.J. Cantliffe, D.J. Huber, J. Ciardi, H.J. Klee. 2005. Transformation of a muskmelon 'Galia' hybrid parental line (*Cucumis melo* L. var. *Reticulatus* Ser.) with an antisense ACC oxidase gene. Plant Cell Reports. Vol. 25, pp. 198-205.

Nunez-Palenius, H.G., D.J. Cantliffe, H.J. Klee, D.J. Huber. 2007. A single insertion of ACC Oxidase gene in antisense orientation extends the shelf life in muskmelon 'Galia' hybrid parental line (*Cucumis melo* L. var. *reticulatus* Ser.). Acta Horticulturae. 2007. Vol. 731, pp. 421-426.

Nunez-Palenius, H.G., D.J. Huber, D.J. Cantliffe, H.J. Klee. 2007. Fruit ripening characteristics in a transgenic 'Galia' male parental muskmelon (*Cucumis melo* L. var. *reticulatus* Ser.) line. Postharvest Biology and Tech. Vol. 44, pp. 95-100.

Further information on ethylene and Flavr Savr ™ Tomato:

Kader, A. 2002. Postharvest technology of horticultural crops, third edition. Univ. of CA, Ag. And Nat. Res. Pub. 3311. Oakland, CA.

Kramer, M. and K. Redenbaugh. 1994. Commercialization of a tomato with an antisense polygalacturonase gene: The FLAVR SAVR™ tomato story. Euphytica. Vol. 79, pp. 293-297.

Further information on glyphosate:

Cerdeira, A.L. and Duke, S.O. 2006. The current status and environmental impacts of glyphosate-resistant crops: a review. J. Environ. Qual. Vol. 35, pp. 1633-1658.

FAO. 2005. pesticide residues in food, report 2005. FAO Plant Production and Protection Paper 183. <http://www.fao.org/docrep/009/a0209e/a0209e00.htm#Contents >